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EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

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Please find below and/or attached an Office communication concerning this application or proceeding.



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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 09/430,289
Filing Date: October 29, 1999
Appellant(s): D'ALESSIO ET AL.

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~~JUN 1 2004~~ corrected
JUL 01 2004
GROUP 1700 Omstone

Joel Armstrong

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/19/2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

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(7) Grouping of Claims

Appellant's brief includes a statement that Group I - claims 1-14, 16-18, 45, 56, 59;

Group II - claims 46-50, do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5785178	Kvidtrud	07-1998
5693283	Fehn	12-1997
3704089	Stehlik	11-1972
4775587	Wallis	10-1988
2791504	Plambeck	05-1957

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Group I

1. Claims 1-9, 16-18, 45-47, 56, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kvidtrud in view of Fehn.

Kvidtrud teaches a container with a dispenser nozzle (squeezable vial with threaded closure cap having a dispensing opening), which can be used for dispensing cyanoacrylate (column 1, lines 30-40) which is a 1-1-disubstituted ethylene monomer. Suitable polymeric materials for making the container (vial) include blowmolded low density polyethylene, high density polyethylene (HDPE) and CO₂R functionalized polyethylene of which polyethylene terephthalate (PET) is a subset (column 3, lines 35-45). Polypropylene is the homolog right next to polyethylene, having 3 methyl groups instead of 2 methyl groups in the repeat unit of the polymer. Kvidtrud et al. teaches that the polymeric material has sufficient memory to enable the sections to recover from deformation and fully return to their original shape once finger pressure is released (column 3, lines 25-35).

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Kvidtrud, however, fails to teach that the inner surface of the container is post-halogenated.

Fehn has a polyethylene container which is post-fluorinated (post-halogenated) (column 4, lines 1-15). One embodiment is a container with a fluorinated inner surface of high density polyethylene (HDPE) made by contacting the HDPE with fluorine gas (column 5, lines 20-35). The fluorine concentration in the polyethylene surface region would thus be higher than the fluorine concentration in the subsurface region.

Fehn teaches that fluorinating a polyethylene surface provides it with a Teflon-like, nonsticky surface with improved resistance to the escape of volatile organic liquids, and a barrier against contaminant migration into the (contents of the) container (column 3, lines 30-40). Therefore it would have been obvious to one of ordinary skill in the art to have used the fluorination process taught by Fehn to fluorinate the inner surface of the polyethylene container of Kvidtrud et al. in order to obtain a container for a 1-1-disubstituted ethylene monomer such as cyanoacrylate, with improved shelf-life due to better containment of the monomer and barrier to contaminants.

2. Claims 10-14, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kvidtrud in view of Fehn as applied to claims 1-9, 16-18, 45-47, 56, 59 above, and further in view of Stehlik.

Kvidtrud has been discussed above, and teaches a container applicator for cyanoacrylates, but fails to specify the alkyl alpha-cyanoacrylates, or teach the sterilization of the container or the presence of halogen-containing acid.

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Stehlik teaches a process for sterilizing (alkyl) alpha-cyanoacrylates with radiation (column 1, lines 20-35), using hydrofluoric acid (hydrogen fluoride) as the Lewis acid inhibitor (column 1, lines 45-50).

Chlorine is the next halogen to fluorine in the Periodic Table. Therefore it would have been obvious to one of ordinary skill in the art to have used hydrochloric acid as an alternate Lewis acid inhibitor, and chlorine as an alternate post-halogenation gas which results in post-chlorination instead of post-fluorination of the polymeric material of the container body.

Stehlik teaches that the alkyl group of the alpha-cyanoacrylate has 1-16 carbon atoms (column 1, lines 25-35) which includes 2-octyl cyanoacrylate. The sterilization process on the combination of the alkyl cyanoacrylate and hydrofluoric acid produces a package combination which has a shelf life of at least about thirty months (should not result in reduced stability within a period of at least one year) (column 1, lines 65-72 and column 2, lines 1-5).

Therefore it would have been obvious to one of ordinary skill in the art to have applied the sterilization process with the combination of the alkyl cyanoacrylate and hydrofluoric acid, as taught by Stehlik, to the cyanoacrylate dispensing container of Kvidtrud et al., in order to obtain a sterilized cyanoacrylate dispensing package which has a shelf life of at least about thirty months.

Group II

Claims 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kvidtrud in view of Walles.

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Kvidtrud has been discussed above, and teaches a polyolefin dispensing container for 1-1-disubstituted ethylene monomer cyanoacrylate (column 1, lines 30-40). Kvidtrud, however, fails to teach the functionalization of the inner surface of the polyolefin container.

Walles teaches SO_3H group functionalization via the use of SO_3 gas of polyethylene terephthalate, polyethylene and polypropylene substrates (column 3, lines 15-30) to decrease the permeability of the container to chemicals (column 1, lines 30-40). C is right next to S in the Periodic Table. Thus CO_2 is the homolog of SO_3 . The introduction of CO_2 would produce the corresponding carboxylic acid CO_2H functionalization of the polyolefin surface.

Walles teaches further reaction (neutralization) with ammonia (abstract) and water (column 5, lines 10-15). One of ordinary skill in the art would have known that ammonia dissolved in water forms ammonium hydroxide, and that the neutralization of the SO_3H group functionality with ammonium hydroxide then forms sulfonamide groups. Walles teaches that the addition of amide (ammonium) functionality to the sulfo (SO_3) functionality improves the effectiveness of the sulfonation treatment (column 1, lines 45-55).

Walles teaches that SO_3 and halogen functionalization of the polyolefin surface decreases permeability of the container to chemicals (column 1, lines 30-45). Therefore it would have been obvious to one of ordinary skill in the art to have used the surface functionalization of polyolefin containers, as taught by Walles, to the cyanoacrylate dispenser of Kvidtrud, in order to obtain a container with an inner functionalized surface with decreased permeability to the cyanoacrylate content.

(11) Response to Argument

Group I

1.a.i. Appellants argue that Kvidtrud et al. does not teach or suggest the use of halogenated or functionalized materials.

Appellants are respectfully reminded that Fehn and Walles are the secondary references which compensate for failure of the primary reference Kvidtrud et al. to teach the halogenation or functionalization of the container material. The motivations to combine the references are addressed below in response to Appellants' arguments against the validity of the combinations.

1.b.i. Appellants argue that Kvidtrud does not suggest that the container is suitable for use with a 1,1-disubstituted ethylene monomer composition such as cyanoacrylate composition as claimed since the disclosure is with reference to the prior art, not to the containers that are the focus of the Kvidtrud patent which is the design of containers which address problems in the prior art, namely that the containers do not allow certain wavelength radiation to enter the container since such radiation would tend to cure the photocurable composition.

From the statements made by Appellants, it may be surmised that Appellants do acknowledge that the containers of Kvidtrud address problems in the prior art. Appellants are respectfully apprised that Kvidtrud titles the section: "Description of related art" ('178, column 1, line 10), meaning that the art described is related to the invention of Kvidtrud. Kvidtrud singles out cyanoacrylate adhesives as the only named chemicals for containment ('178, column 1, lines 30-40).

1.b.ii. Appellants argue that Kvidtrud does not teach or suggest that cyanoacrylate adhesives are readily curable by visible light.

Appellants are respectfully reminded that cyanoacrylate adhesives are inherently photocurable via a free radical process, being ethylenically unsaturated, as further evidenced by Plambeck ('504, column 17, lines 70-75) (presented in the Office action dated 12/23/2003). Although the adhesives do not cure instantaneously as when they polymerize anionically via water initiation, the slower photocuring over time shortens shelf life, which is the main concern of Kvidtrud.

2.a.i. Appellants argue that the declarations of Applicant show that the post-halogenation process does not provide absolute physical barriers to chemical species, and that it does not exhibit reduced moisture vapor transmission rates while providing improved shelf-life to the container and the contents.

From the statements made by Appellants, it may be surmised that Appellants are merely clarifying that the declarations are to demonstrate that the post-fluorination does not increase the barrier to moisture vapor transmission, not to invalidate Fehn, since Appellants do cite Fehn as an exemplary reference for post-fluorinating a material in the specification.

2.a.ii. Appellants argue that Fehn uses the post-fluorinated material as a barrier layer to prevent migration of contaminants into the contained materials, and not to block water vapor transmission.

From the statements made by Appellants, it may be surmised that Appellants concur that Fehn does not teach against the use of the post-fluorinated container for containment of the cyanoacrylate. Appellants are respectfully apprised that contaminants can reduce shelf-life of the contained materials, by acting as catalysts for undesirable reactions, such as photocuring, as evidenced by Plambeck ('504, column 17, lines 70-75). The post-fluorination process of Fehn is

therefore applicable for improving the stable containment of photocurable materials in the container of Kvidtrud.

2.b.i. Appellants argue that the declarations establish that post-fluorination does not provide a barrier to moisture vapor transmission – a species known to cause rapid polymerization of cyanoacrylate adhesives.

Appellants are respectfully reminded that, although the declarations provide data showing that the post-fluorination process does not reduce the rate of moisture vapor transmission of the polyolefin container, Appellants have not demonstrated that the barrier does not increase shelf-life by functioning to prevent the contained cyanoacrylate from escaping, and to prevent other contaminants, aside from moisture vapor, from migrating into the contents.

2.c.i. Appellants argue that Kvidtrud and Fehn are directed to non-analogous art from the present application and from each other, comparing Kvidtrud which is directed to a special container that prevents certain radiation from entering the container because such radiation would tend to cure a photocurable material contained in the container, with Fehn which is directed to a container made from post-consumer recycled material, where the post-halogenated material is applied to the inside of the container to prevent contaminants from entering the contents.

Appellants are respectfully reminded that Kvidtrud teaches that the containment of cyanoacrylate adhesives is a problem, and proposes a polyolefin container for it. Fehn teaches that a post-fluorinated polyolefin container provides a barrier both to the escape of volatile organic liquids from the interior of the container, and to the migration of contaminants from the plastic to the interior contents. Fehn is directed to the barrier of organic compounds, both polar

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and nonpolar ('283, column 5, lines 60-70) which is ideal for the prevention of the escape of cyanoacrylates, which are volatile polar organic compounds, to the outside of the container; and for the prevention of contaminant migration into the contents of the container ('283, column 3, lines 30-40). Thus Fehn and Kvidtrud are both directed to the containment and preservation of the integrity of the original contents, which is synonymous with the shelf life of the contained materials. Therefore they are analogous art, and pertinent to the present application.

2.c.ii. Appellants argue that Kvidtrud is specifically directed to the containment of substances that are readily curable by visible light, while Fehn is directed to protecting any contained substances from contaminants present in post-consumer recycled plastic materials, which may or may not be polar organic compounds, and is in no way limited to compounds like the photo-curable compounds of Kvidtrud, citing the materials used in the testing process of Fehn.

Appellants are respectfully apprised that the fact that Fehn is directed to protecting any contained substance from contaminants, which can be both polar and non-polar organic compounds, is great motivation, since it would be difficult to determine the nature of all the contaminants present, and to ascertain all those which would contribute to reduce the shelf-life of the contained material. Fehn evaluated the barrier to each of the four classes of organic contaminants recommended by the FDA ('283, column 5, lines 60-70). Cyanoacrylate tissue adhesives are used in-vivo as taught by Stehlik ('089, column 1, lines 15-20). Chemicals introduced inside the human body fall under the jurisdiction of the FDA (Food and Drug Administration). The containers for cyanoacrylate tissue adhesives would therefore have to pass testing standards set by the FDA.

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2.c.iii. Appellants argue that since Fehn does not mention photo-curable compounds as is the focus of Kvidtrud, they are non-analogous art.

Appellants are respectfully reminded that Fehn is directed to the barrier to the escape of the contained compounds, and to the migration of contaminants into the contents. It is an advantage for the barrier to function against a variety of chemicals and contaminants since it would be difficult to ascertain all the contaminants present and their effects on the contained materials. Both Kvidtrud and Fehn are directed to the shelf-life of the contained compounds, as established above. They are therefore analogous art.

2.d. i. Appellants argue that Kvidtrud does not teach or suggest that any improvement is required to provide the fluorinated barrier layer of Fehn; instead Kvidtrud is made from materials that are meant to block visible light and actinic radiation.

Appellants are respectfully reminded that Fehn provides a barrier which functions against a variety of chemicals and contaminants. This is a great advantage since it would be difficult to ascertain all the contaminants present and their effects on the contained materials. Both Kvidtrud and Fehn are directed to the shelf-life of the contained compounds. Therefore, there is motivation to combine.

2.d.ii. Appellants argue that neither Kvidtrud nor Fehn address whether the combination would even be suitable for the objectives of Kvidtrud as neither reference addresses whether the fluorination would have any adverse impact on the photocurable composition.

Appellants are respectfully apprised that since both references do not teach any adverse impact of fluorination on the contents, they do not teach against its use.

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2.d.iii. Appellants argue that even if the combination is proper because Fehn provides improved barrier properties, neither reference suggests that the container of Kvidtrud requires such additional barrier properties.

Appellants are respectfully reminded that one of ordinary skill in the art knows that marketing is always striving for improvement to obtain an edge over the competitor. Increased shelf life of a product in the packaging art for reactive materials is very much in demand and thus subject to improvement.

2.d.iv. Appellants argue that the motivation for combining the references must include an expectation of success when the combination is made, that the reactivity of 1,1-disubstituted adhesives is well known in the art, but that neither reference teaches that the principles of Fehn could be successfully applied to the containment of such reactive materials.

Appellants are respectfully reminded that the fact that Fehn's barrier functions against a variety of chemicals and contaminants is the motivation to apply it to the container of Kvidtrud. One of ordinary skill in the art knows that the more reactive a material is, the more contaminants will cause it to react. Thus the reduction of contaminants will prolong its shelf life and reduce its rate of change in properties, one of them being its viscosity.

2.e.1) Appellants argue that some of Kvidtrud's container materials can not be post-fluorinated, that at least PET and PETG are not post-fluorinable.

Appellants are respectfully reminded that PET is claimed by Applicant as a container material which has been post-fluorinated (claim 7). Appellants' statement raises the question of lack of enablement of the present application for the subject matter of claim 7.

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2.e.2) Appellants argue that Kvidtrud's pigmented containers could not be easily post-fluorinated as is known in the art.

Appellants are respectfully apprised that Fluoro-Seal does teach that it has successfully fluorinated every color imaginable, including some pearlescent pigments (Q. Can pigmented bottles be fluorinated, Page 8). The teaching of "Absolute optimum barrier is always obtained with natural unpigmented resin" must be coupled with the teaching of "fluorination level may have to be bumped up in some instances to match barrier performance of all natural resin" in the same section. Thus Fluor-Seal does teach that there is reasonable expectation of success.

3. Appellants' arguments against Stehlik are directed against the valid combination of Kvidtrud and Fehn, and have been addressed above.

Therefore, the Examiner respectfully submits that claims 1-14, 16-18, 45, 56, 59 should be rejected since the scope of the claims falls within the limitation of the existing art.

Group II

i. Appellants argue that there is no teaching that further improved barrier properties are required for the container of Kvidtrud.

Appellants are respectfully reminded that one of ordinary skill in the art knows that marketing is always striving for improvement to obtain an edge over the competitor. Increased shelf life of a highly reactive product is very much in demand and thus subject to improvement.

ii. Appellants argue that the references do not teach how the SO₃ gas of Walles would affect the contained photocurable composition of Kvidtrud.

Appellants are respectfully apprised that the fact that the references fail to mention any adverse effect means that they do not teach against applying the functionalization process of Walles to the container of Kvidtrud.

Furthermore, Walles teaches that SO_3 and halogen functionalization of the polyolefin surface decreases permeability of the container to chemicals ('587, column 1, lines 30-45). Therefore the motivation is provided to use the surface functionalization of polyolefin containers as taught by Walles in the invention of Kvidtrud et al. in order to obtain a container with an inner functionalized surface with decreased permeability to the cyanoacrylate contained.

iii. Appellants argue that to provide an impermeable barrier in the inside of the container is specifically contrary to the moisture vapor transmission rates provided by Appellants.

Appellants are respectfully reminded that although the declarations (dated 6/21/02 and 12/09/02) provide data showing that the post-fluorination process does not reduce the rate of moisture vapor transmission of the polyolefin container, no data was presented for the other surface functionalization processes apart from post-fluorination. Furthermore, Appellants have not demonstrated that the prevention from escape of the cyanoacrylate and the prevention from migration of other contaminants from the plastic does not reduce shelf-life.

Therefore, the Examiner respectfully submits that claims 45-50 should be rejected since the scope of the claims falls within the limitation of the existing art. Thus, after considering all the evidence, it is still the examiner's position that the rejections are appropriate.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

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June 25, 2004

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